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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/633,573	08/04/2000	Wilson T. Asfora	M190.236.101 / P0030090.0	2575
7590 12/10/2007 Dicke, Billig & Czaja, PLLC ATTN: MD Matters Fifth Street Towers, Suite 2250 100 South Fifth Street Minneapolis, MN 55415			EXAMINER STIGELL, THEODORE J	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 12/10/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/633,573

Applicant(s)

ASFORA, WILSON T.

Examiner

Theodore J. Stigell

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-9,11,12,34,35,38,39 and 42-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-9,11,12,34,35,38,39 and 42-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____                                                         | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

#### ***Claim Objections***

Claim 2 is objected to because of the following informalities: There appears to be a typo on line 2 of claim 2. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

***Claims 1-2 are*** rejected under 35 U.S.C. 103(a) as being unpatentable over Swann et al. (4,646,752) in view of Fleckenstein (6,454,774) and Deutsch et al. (4,480,997). Swann discloses a subdural evacuating port comprising a tubular portion (14) for partial insertion into an opening in a skull of a patient, the tubular portion having a proximal end and distal end and a lumen extending between the proximal and distal ends, the tubular portion having an exterior surface with threads, a hub (20) for

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facilitating rotation of the tubular portion, and retaining means (18) on the exterior surface of the tubular portion adjacent to the distal end for engaging and retaining a conduit (7) on the distal end of the tubular portion, wherein the hub is mounted between the ends of the tubular portion. Swann does not disclose wherein the threads are self-tapping and include a longitudinal groove extending through the threads to form a cutting surface. Swann also does not disclose a pair of wings for facilitating rotation of the tubular portion.

Fleckenstein discloses a device for accessing an internal region of a patient's brain. Fleckenstein teaches to include skull-screw wings (9) to assist in the insertion threading procedure (See column 4, lines 41-42).

Deutsch discloses a dental post that includes self-tapping threads (18) and a longitudinal groove (24) extending through the threads that creates a cutting surface. Deutsch discloses that this configuration is useful in creating a corresponding thread in a body part.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Swann with the wings of Fleckenstein and the self-tapping threads of Deutsch to create a subdural evacuating port that is more easily inserted in the body and ensures a tighter connection to the skull.

**Claims 4-5, 34-35, 42, and 44-48 are** rejected under 35 U.S.C. 103(a) as being unpatentable over Swann et al. (4,646,752), Fleckenstein (6,454,774), and Deutsch et al. (4,480,997) in further view of Akers (3,650,551). Swann, Fleckenstein, and Deutsch in combination disclose all of the limitations recited in the independent claims, but they

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fail to disclose retaining means that include a plurality of annular barbs comprising a frustoconical surface for retaining a conduit.

Akers discloses a threaded fitting comprising retaining means (26) that includes a plurality of annular barbs with a frustoconical surface. Akers discloses that this configuration is useful in retaining a conduit thereon.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination of Swann, Fleckenstein, and Deutsch with the retaining means of Akers to create a subdural evacuating port that provides a better connection to a fluid tube.

**Claims 6-9 and 38-39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Swann et al. (4,646,752), Fleckenstein (6,454,774), Deutsch et al. (4,480,997), and Akers (3,650,551) in view of Lake (3,766,910). Swann, Fleckenstein, Deutsch, and Akers in combination disclose most of the limitations recited in the independent claims but fail to disclose a retractor for spacing sides of an incision in a scalp away from each other.

Lake discloses a disposable delicate tissue retractor comprising a pair of arms (12, 80) each having a proximal ends (no reference numeral; see Figures 2 or 9) joined together to form an apex, each of the arms extending away from the apex such that distal ends (no reference numeral; see Figures 2 and 9) of the arms are spaced from each other, the arms of the retractor forming a substantially V-shaped configuration.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space as taught by Swann,

Fleckenstein, Deutsch, and Akers, by incorporating a retractor such as that which is taught by Lake, so as to allow for exposure of an adequate operative field to aid in proper placement of the subdural evacuating port in the patient's skull.

**Claims 11-12 and 43 are** rejected under 35 U.S.C. 103(a) as being unpatentable over Swann et al. (4,646,752), Fleckenstein (6,454,774), Deutsch et al. (4,480,997), Akers (3,650,551), and Lake (3,766,910) in further view of McNeil (4,828,546). Swann, Fleckenstein, Deutsch, Akers, and Lake in combination disclose all of the limitations recited in the independent claims but fail to disclose a negative pressure device comprising a Jackson-Pratt bulb.

McNeil et al. discloses a bulb evacuator for closed wound suction comprising an interior, a primary opening (20, 21) and a secondary opening (24) providing communication between the interior and an exterior of the bulb, a check valve (23) in communication with the primary opening for resisting exit of fluid from the interior of the bulb to the exterior of the bulb while permitting fluid flow into the interior through the primary opening, and a cap (25) for selectively closing the secondary opening of the bulb.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space taught by Swann et al. (4,646,752), Fleckenstein (6,454,774), Deutsch et al. (4,480,997), Akers, and Lake (3,766,910) by incorporating a bulb evacuator as disclosed by McNeil et al., so as to provide adaptable means for draining fluid causing high intracranial pressure which is characterized by its ease of operation.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 2, 4-9, 11, 12, 34, 35, 38, 39 and 42-48 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Theodore J. Stigell

  
**NICHOLAS D. LUCCHESI**  
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